



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Ointment for the Topical Administration to Ischemic Treat and/or Neuropathic Ulcers in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Emmaus Medical Inc. located in 21250 Hawthorne Boulevard, Suite 800, Torrance, CA, 90503.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Edward Fenn, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, Telephone: 240-276-6833 or E-mail: Tedd.Fenn@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- I. United States Provisional Patent Application No. 62/077,622 filed Nov. 10, 2014, “Topical Sodium Nitrite Formulations”, [HHS Ref. No. E-149-2014-0-US-01];
- II. International Patent Application No. PCT/US2015/060015 filed Nov. 10, 2015, “Topical Sodium Nitrite Formulations”, [HHS Reference No. E-149-2014-0-PCT-02];
- III. European National Stage Patent Application No. 15798623.3, filed Nov. 10, 2015, “Topical Sodium Nitrite Formulations”, [HHS Ref. No. E-149-2014-0-EP-03];
- IV. U.S. National Stage Patent Application No. 15/525,557 filed May 9, 2017, “Topical Sodium Nitrite Formulations”, [HHS Ref. No. E-149-2014-0-US-04];

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be the United States only and the field of use may be limited to the following:

“Treatment of neuropathic and/or ischemic skin ulcers in humans”.

This technology discloses a topical ointment formulation comprising about .5% to 3.0% by weight non-acidified sodium nitrite dispersed in white petrolatum, mineral oil and bisabolol for topical administration. Nitrite anions may act as a vasodilator in vivo by generating nitric oxide (NO) in tissues with lower oxygen tension and pH. Therapeutic application of sodium nitrite through this specific topical formulation may provide selective vasodilation to hypoxemic tissue that treat ulcers associated with chronic ischemic and neuropathic ulcer conditions associated with several diseases.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: June 12, 2020.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

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